

Application Serial No. 09/807,704  
Reply to Office Action of June 18, 2007

PATENT  
Docket No. CU-2513

### REMARKS/ARGUMENTS

Reconsideration is respectfully requested.

Claims 35-52 are pending in the present application before this amendment. By the present amendment, claim 20 has been amended. New claim 53-54 have been added. No new matter has been added.

Support for the limitation in new claim 53 of "*freezing the biological material such as to make membranes surrounding cells in the frozen biological material brittle and rupture to liberate contents of the cells*" can be found in the specification, inter alia, at page 5 lines 26-30.

Support for the limitation in new claim 53 of "*wherein the freezing step of the biological material is frozen to a temperature of 0°C to -50°C*" can be found in the specification, inter alia, at page 5 lines 26-37.

Support for the limitation in new claim 53 of "*wherein the freezing step is performed at a rate of about -1 °C / minute*" can be found in the specification, inter alia, at page 5 lines 34-37.

Support for the limitation in new claim 53 of "*wherein the thawing step is performed using heating selected from the group consisting of microwave heating, heat exchanging heating, infra red heating, and electric conduction heating*" can be found in the specification, inter alia, at page 5 lines 4-7

Support for the limitation in new claim 53 of "*treating mechanically the frozen biological material to produce particles having a mean particle diameter not exceeding 50 millimeters*" can be found in the specification, inter alia, at page 7 lines 13-16.

Support for the limitation in new claim 53 of "*thawing the treated biological material to a first temperature*" can be found in the specification, inter alia, Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "*separating oil from the thawed biological material at the first temperature*" can be found in the specification, inter alia, at Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "*estimating a first yield of oil from the*

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*thawed biological material at the first temperature*" can be found in the specification, inter alia, at Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "warming the treated biological material to another temperature" can be found in the specification, inter alia, at Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "*isolating oil from the thawed biological material at the another temperature*" can be found in the specification, inter alia, at Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "*calculating another yield of oil from the thawed biological material at the another temperature*" can be found in the specification, inter alia, at Example 2 at page 14 line 3 to page 15 line 14 which includes Table 1.

Support for the limitation in new claim 53 of "*optimizing an extraction temperature to separate oil from the biological material by considering factors selected from the group consisting of oil yields, peroxide concentration numbers, percentages of free fatty acid, vitamin A concentrations, viscosity and anisidine values*" can be found in the specification, inter alia, at page 17-20 tables 5-9 and Figures 2-3.

Support for the limitation in new claim 53 that "*the biological material is selected from the group consisting of fish liver, whale blubber, soy beans, sunflower seeds, olive seeds, corn seeds, algae, yeast, cell culture material, and bacteria*" can be found in the specification, inter alia, at at page 5 lines 9-13 and page 13 lines 22-24.

Support for the limitation in new claim 54 "*the enzyme is selected from the group consisting of cellulase, collagenase and lysozyme*" can be found in the specification, inter alia, at page 5 lines 16-20

Support for the limitation in new claim 54 that the "*solvent is hexane*" can be found in the specification, inter alia, at page 5 lines 16-20

Support for the limitation in new claim 54 that "*the emulsion-bursting material is salt*" can be found in the specification, inter alia, at page 5 lines 16-20

Support for the limitation in new claim 54 that "*the first temperature is between about 10 °C to about 15 °C*" can be found in the specification, inter alia, at Table 1 at

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page 15.

Support for the limitation in new claim 54 of the step of "*avoiding forming three phases in which the three phases comprise a proteinaceous phase, a free water phase, and an oil phase*" can be found in the specification, inter alia, at page 9 lines 5-7

Support for the limitation in new claim 54 of the step of "*determining a denaturing temperature by visually inspecting the oil for visible stringy agglomerates and agglomerate precipitates*" can be found in the specification, inter alia, at page 11 lines 10-19

Support for the limitation in new claim 54 of the steps of "*refining the oil; deodorizing the oil; and adding an antioxidant containing tocopherol to the oil*" can be found in the specification, inter alia, at page 17 Example 5 lines 13-17 and at page 18 Table 6.

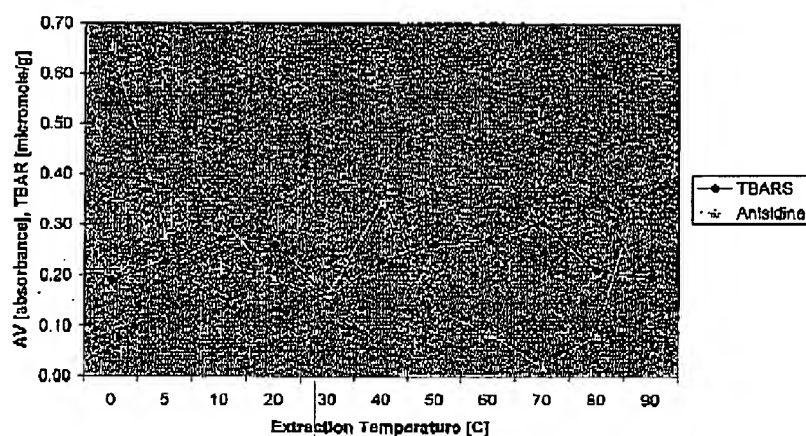
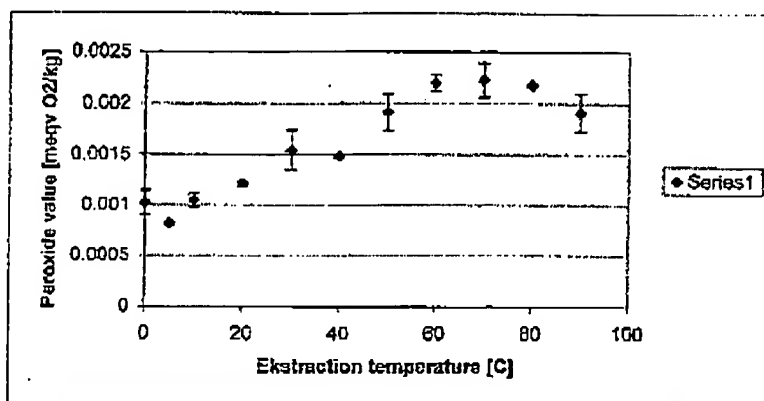
In the office action, claims 35-52 stands objected under 35 U.S.C. § 103(a) as being unpatentable over Jannson (No. Patent Application Number 1993 3009) in view of Keyes (US 4,713,335).

For the reasons presented below, the Applicant respectfully traverses this obviousness rejection of claims 35-52, and submits that the claims, as they now stand, are in allowable form.

The Examiner's attention is respectfully directed to the following graphs that depict comparison tests for extracted oil from fish at low and elevated temperatures. Please note that the presented results show tests done at temperatures also above 60°C but the results show clearly that the yield and speed of extraction are improved at elevated temperatures. Also, please note that the quality of the oil shows no significant changes (as expressed through the results of the included Fe). Even though some of the data show fluctuations, this is on account of the test methods were not being particularly suited for the small amounts of the relevant substances.

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The results support the conclusion that a significant improvement of performing oil separation at elevated temperatures (but below the denaturation temperature of the proteins). Determination of the denaturation temperature and performing the separation slightly below this temperature is not, as far as the Applicant can determine (and previously pointed out to the Examiner), disclosed anywhere in the prior art documents. The presently presented data, combined with the fact that the industry has not previously attempted to perform the oil separation at such elevated temperatures despite the significant advantages gains from this, should prove that such a separation indeed is novel and nonobvious which should establish inventive merit.

Further concerning the **unexpected and surprising** results when employing the method according to the present invention, i.e., the process of leaching/separating animal/fish oil at optimal temperatures derived from the experimental results depicted in

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the above figures, the Applicant points out that these results should be viewed as a whole. That is, the Applicant respectfully submits that it is surprising that ALL of the values do not show deterioration of the oil quality despite the fact that oil extraction at high temperature is known to produce oil at a poorer quality. This is indeed the cause of the previous known oil extraction techniques that have not been performed at elevated/optimal temperatures, such as the known steam-leaching of the oil previously known technique.

The Applicant therefore respectfully submits that it is surprising that a higher extraction rate may be obtained without harming the quality of the oil when employing the presently claimed invention. Again the crux of the matter is finding the optimal temperature of the extraction process by finding the denaturation temperature of the proteins (by observation and/or viscosity measurements as indicated in the present application). Also it is surprising that it is the denaturation/agglomeration temperature of the PROTEINS that determines the optimal extraction temperature and not some other (lower) temperature at which other components might start to deteriorate (See e.g., the present disclosed application at page 11, lines 15-19).

Thus determining the optimal temperature at which the extraction may be performed will substantially increase the effect and rate of the extraction, even if such a temperature is just a number of degrees above the previously used extraction temperature.

Concerning the previously used temperatures that have been used for extracting oil, the example in the Jannson 1993 3009 patent, substantially relied on by the Examiner, indicated temperatures of 6 °C (Example 1 in the Jannson 1993 3009 patent) and 10 °C (Example 2 and 3 in the Jannson 1993 3009 patent) as opposed to 28 °C according to the examples in the present application (See Example 1 in the present application). The other examples in the present application indicate how to determine the optimal extraction temperature of the oil to obtain high-quality oil at increased extraction rates.

Therefore, the Applicant respectfully submits that claims 35-52 are in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw this

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obviousness rejection to claims 35-52.

Regarding new claim 53, the Examiner's attention is respectfully directed towards the following emphasized limitation of new independent claim 53:

**CLAIM 53**

An improved separation process for production of oil from a biological material, the process comprising the steps of:

**freezing** the biological material such as to make membranes surrounding cells in the frozen biological material brittle and rupture to liberate contents of the cells wherein the freezing step the biological material is frozen to a temperature of 0°C to -50°C wherein the freezing step is performed at a rate of about -1 °C / minute;

**treating** mechanically the frozen biological material to produce particles having a mean particle diameter not exceeding 50 millimeters wherein the step of treating mechanically of the material is at least one of the group consisting of grinding, milling, chopping and pressing;

**thawing** the treated biological material to a first temperature wherein the thawing step is performed using heating selected from the group consisting of microwave heating, heat exchanging heating, infra-red heating, and electric conduction heating;

**separating** oil from the thawed biological material at the first temperature;

**estimating** a first yield of oil from the thawed biological material at the first temperature;

**warming** the treated biological material to another temperature;

**isolating** oil from the thawed biological material at the another temperature;

**calculating** another yield of oil from the thawed biological material at the another temperature; and

**optimizing** an extraction temperature to separate oil from the biological material by considering factors selected from the group consisting of oil yields, peroxide concentration numbers, percentages of free fatty acid, vitamin A concentrations, viscosity and anisidine values,

wherein the biological material is selected from the group consisting of fish liver, whale blubber, soy beans, sunflower seeds, olive seeds, corn seeds, algae, yeast, cell culture material, and bacteria.

The Applicant respectfully submits that Jannson and Keyes, in whole or in combination, do not teach or suggest, *inter alia*, the above-emphasized limitations of new independent claim 53. In particularly, both Jannson and Keyes, in whole or in combination, do not teach or suggest the limitations of *warming the treated biological material [again] at another temperature*. Further, both Jannson and Keyes, in whole or in combination, do not teach or suggest the limitation of *"isolating oil from the thawed biological material at the another temperature."* Still further, both Jannson and Keyes, in whole or in combination, do not teach or suggest the limitation of *"optimizing an extraction temperature to separate oil from the biological material by considering factors*

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*selected from the group consisting of oil yields, peroxide concentration numbers, percentages of free fatty acid, vitamin A concentrations, viscosity and anisidine values."*

Instead Jannson is used in the Office Action to suggest that low-temperatures should be used within its process not to denature the protein. (Office Action page 3 lines 2-3). Further Jannson is used in the Office Action to teach a process of separating elements from biological material to obtain high yields of non-denatured protein, fats or lipids subsequent to the steps of freezing and mechanically treating the biological material. (See Office Action page 3 lines 5-13). The Applicant can find nothing within Jannson that teaches or suggests, *inter alia*, any of the above-emphasized limitations.

In contrast to the presently claimed invention, Keyes is used by the Office Action to teach viscosity measurements to monitor protein denaturation and/or determine the denaturing temperature within a material (Office Action page 5, lines 1-3). The Applicant can find nothing within Keyes that teaches or suggests, *inter alia*, any of the above-emphasized limitations.

As per MPEP §2143.03, the combined references must teach or suggest all of the claimed limitations. Since Jannson and Keyes, in whole or in combination, do not teach or suggest, *inter alia*, the limitation of "*warming the treated biological material [again] at another temperature*"; the limitation of "*isolating oil from the thawed biological material at the another temperature*"; and limitation of "*optimizing an extraction temperature to separate oil from the biological material by considering factors selected from the group consisting of oil yields, peroxide concentration numbers, percentages of free fatty acid, vitamin A concentrations, viscosity and anisidine values*" then Jannson and Keyes, in whole or in combination, cannot support an obviousness rejection to independent claim 53, as amended.

The Applicant therefore respectfully submits that independent claim 53 is in allowable form.

Claim 54 depends upon independent claim 53, and as such, incorporates by reference all the claimed limitations contained therein, including the above emphasized limitations that have already been shown to be absent from Jannson and Keyes, in

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whole or in combination. The Applicant therefore respectfully submits that dependent claim 54 is in allowable form.

For the reasons set forth above, the Applicant respectfully submits that claims 35-52 and new claims 53-54, now pending in this application, are in condition for allowance over the cited references. Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections and earnestly solicits an indication of allowable subject matter. This amendment is considered to be responsive to all points raised in the office action.

Should the Examiner have any remaining questions or concerns, the Examiner is encouraged to contact the undersigned attorney by telephone to expeditiously resolve such concerns.

Respectfully submitted,

Dated: DECEMBER 18, 2007



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